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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,681

Applicant(s)

PHADTARE ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10,12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. In response to the previous Office actions, a Final rejection (Paper No. 12 mailed on May 23, 2003), Applicants filed an after-final amendment received on August 18, 2003 (Paper No. 13). Said amendment had not been entered as noted in an Advisory action (Paper No. 14 mailed on August 29, 2003). However, said amendment has now been entered with the filing of a request for continued examination (Paper No. 15 received September 22, 2003). Said amendment amended Claims 7 and 8 and added new Claim 15. Thus, Claims 7, 8, 10, 12, and 15 are pending in the instant Office action.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 7, 8, 10, and 12, drawn to a *dep* gene and related products, classified in class 536, subclass 23.7.
 - II. Claim 15, drawn to method of conferring resistance to DHCP, classified in class 435, subclass 471.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. §

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806.05(h)). In the instant case, the product can be used for a materially different process of using the product, such as in recombinant production of the DHCP efflux protein. Thus, Groups I and II are patentably distinct. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Notice of Possible Rejoinder. The Examiner notes that if product claims in Group I are found directed to an allowable product, then process claims in Group II, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

5. Newly submitted Claim 15 directed to an invention that is independent or distinct from the invention originally claimed for the reasons cited above. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claim 15 is withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

6. Claims 7, 8, 10, 12, and 15 are pending. Claim 15 is withdrawn from further consideration as a non-elected invention. Claims 7, 8, 10 and 12 will be examined herein.

Priority

7. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/228,727 filed on August 29, 2000. The Examiner notes that the protein sequence of the claimed DHCP efflux protein is disclosed in said provisional application, but not the encoding DNA sequence itself as being examined herein.

Drawings

8. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Withdrawn - Claim Objections

9. Previous objection to Claim 8 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' amendment. Presently, the limitation of "native to *E. coli*" further defines the gene that encodes SEQ ID NO:3.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

10. Previous rejection of Claim 8 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "from *E. coli*" is withdrawn by virtue of Applicants' amendment to "native to *E. coli*".

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11. Previous rejection of Claims 7, 8, 10, and 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation "DHCP" is withdrawn by virtue of Applicant's amendment inserting the definition of DHCP into the first pending claim.

(New) Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. (New) Claims 7, 8, 10, and 12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claims 7 and 10, the phrase "the amino acid sequence (SEQ ID NO:3)" is used; the parentheses render the language unclear as to whether the SEQ ID NO is a real limitation. The Examiner suggests ---the amino acid sequence that is SEQ ID NO:3--- for clarity.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. (New) Claim 8 is rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application

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was filed, had possession of the claimed invention. Claim 8 is drawn to a gene that encodes SEQ ID NO:3 that is native to *E. coli*.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

In the specification, a single example of a gene encoding a DHCP efflux protein from *E. coli* is described – that is, SEQ ID NO:2. No examples of other *E. coli* sequences are described, either *dep* gene sequences or general *E. coli* sequences. The instant claims are drawn to a *subgenus* of all *dep* genes within the claimed structural limitations (encoding SEQ ID NO:3), wherein the DNA must be from *E. coli*. The specification does not describe *E. coli dep* gene sequences to the exclusion of *dep* gene sequences from other sources. Clearly, *dep* gene sequences from *E. coli* within the structural limitations are enabled by the disclosure; however, one of skill in the art would be unable to recognize other members of the claimed subgenus to the exclusion of, for example, *dep* gene sequences from coryneform, within the structural limitations. Thus, the claimed subgenus does not have adequate written description. The Examiner suggests the inclusion of the structural limitation, SEQ ID NO:2, to obviate the instant rejection.

Maintained - Claim Rejections - 35 U.S.C. § 102

14. Previous rejection of Claims 7-8 under 35 U.S.C. § 102(b) as being anticipated by Blattner *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue "the identification and characterization of open reading-frame 389 (*dep*) as responsible for resistance to DHCP in a multi-copy plasmid is not anticipated by the identification of the genome sequence of *E. coli* K-12 as described in Blattner *et al.*" The Examiner neither agrees nor disagrees with this statement since it is not at issue. Claims 7 and 8 are drawn to product claims with open language. As such, Blattner *et al.* clearly anticipates claims to DNA comprising the *dep* gene of *E. coli*. Applicants also argue that Blattner *et al.* do not characterize the ORF named *dep*. Again, the Examiner notes that this is not at issue for the product claims as written since the claimed function is inherent in the structure of the product taught by Blattner *et al.* Applicants argue that no start or stop regions are identified by Blattner *et al.*; the Examiner agrees. However, the open claim language does not require the **only** the *dep* gene be defined, and the DNA fragment that contains the *dep* gene is sufficient to anticipate Claims 7-8.

Applicants further argue, by way of *Amgen*, that it was not "obvious to try" to isolate the *dep* gene from the disclosure of Blattner *et al.* This argument is moot in an anticipatory rejection.

Applicants further argue that not each and every limitation is taught by the art; the Examiner disagrees. Since the sequence of the *dep* gene is exactly taught in the art and since all

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the function described in the specification and reiterated in the claims are inherent in the structure disclosed by Blattner *et al.*, every limitation is taught in the art.

Applicants further argue that Blattner *et al.* does not enable the invention. The Examiner disagrees since the sequence is clearly taught. Applicants continue to argue about now indication of an encoded protein; however, for the open language in Claims 7 and 8, none is necessary for the art to anticipate the claims.

Applicants further argue, “an inherent limitation is one that is necessarily recognized by those skilled in the art and that invalidation based on inherency can not be established by probabilities or possibilities”. It is a clear fact that the *dep* gene taught by Blattner *et al.* encodes a DHCP efflux protein. The fact that Blattner *et al.* do not teach this is irrelevant because the thing that is being claimed, namely a gene encoding SEQ ID NO:3, is clearly anticipated in the teachings of Blattner *et al.* The other “limitations” in the claim merely describe the protein but do not further limit the protein, such that said protein would need to be inherently described by the art.

Applicants further argue that the *dep* gene, as taught by Blattner *et al.*, is a “contaminant” as noted in *In re Coordinated Pre-trial Proceedings in Antibiotics Antitrust Actions*. The Examiner fails to see how a named open reading frame (*vdhC*) encoding an unidentified “putative transporter” can be considered a “contaminant” based solely on the lack of a specific function in the teachings of Blattner *et al.* This argument is not persuasive.

For all of the above reasons, claims to the product that is the *dep* gene are anticipated.

Maintained - Claim Rejections - 35 U.S.C. § 103

15. Previous rejection of Claims 10 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Blattner *et al.* in view of Weickert *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive.

Firstly, by way of clarification, ydhC is found in GenBank Accession Number AE000261 (see PTO-892) as the fifth "CDS" in this region of the *E. coli* genome as noted in the "Features" section. Applicants note that ydhC is known in the art as a bicyclomycin resistance protein and not a "putative transport membrane protein". These two functions are not mutually exclusive since resistance proteins are typically membrane transport proteins to help extrude toxins from within cells, just as described for SEQ ID NO:3, a DHCP efflux protein.

Applicants argue that because Blattner *et al.* have not described the sequence as a DHCP efflux protein that there can be no motivation to express the protein in a multicopy plasmid. The Examiner disagrees on two levels. Firstly, Blattner *et al.* do describe the sequence as an open reading frame encoding a protein with putative transport function (see GenBank Accession Number AE000261). Secondly, Weickert *et al.* provide the motivation for all open reading frames of unknown function. Applicants argue that the motivation in Blattner *et al.* that was previously cited is merely a "motivation to try"; however, Applicants have presented reasoning why the open reading frame taught by Blattner *et al.* cannot be inserted into a multicopy plasmid, since that is all that needs to be enabled to be able to combine the above references. Applicants are reminded that the only the product needs to be obviated, not any methods resulting from said product.

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Summary of Pending Issues

16. The following is a summary of the issues pending in the instant application:
- a) Claim 15 is withdrawn from consideration as a non-elected invention.
 - b) Claims 7, 8, 10, and 12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the parentheses.
 - c) Claim 8 stands rejected under 35 U.S.C. § 112, first paragraph, written description.
 - d) Claims 7-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Blattner *et al.*
 - e) Claims 10 and 12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Blattner *et al.* in view of Weickert *et al.*


Conclusion

17. Claims 7, 8, 10, and 12 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution. The instant Office action is **non-final**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Kathleen M Kerr
Examiner
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November 25, 2003